

PATENT COOPERATION TREATY



PCT**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 07 NOV 2006

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Applicant's or agent's file reference 1702 WO		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/US2005/021234		International filing date (day/month/year) 15.06.2005	Priority date (day/month/year) 06.07.2004	
International Patent Classification (IPC) or national classification and IPC INV. B65D83/14				
Applicant MALLINCKRODT BAKER, INC. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 11 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 15.03.2006		Date of completion of this report 06.11.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Janosch, Joachim Telephone No. +49 89 2399-7525 		

**INTERNATIONAL PRELIMINARY REPORT
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International application No.
PCT/US2005/021234

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-13 as originally filed

Claims, Numbers

1-29 as originally filed

Drawings, Sheets

1-5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 10, 14

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).

☒ no international search report has been established for the said claims Nos. 10, 14

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☒ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☒ complied with.
 - ☐ not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-9, 11-13, 15-29 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-9,11-13,15-29
	No: Claims	
Inventive step (IS)	Yes: Claims	11-13,15-29
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9,11-13,15-29
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

This authority found (cf. item 4 below) that the international application contains more than one invention or groups of inventions, which are not linked by one general inventive concept (Rule 13.1 PCT). Therefore the search report is not complete. Accordingly a preliminary examination of the non-searched subject-matter is not possible (Rule 70.2 (d) PCT).

Re Item IV

Lack of unity of invention

- 1 The present application relates to several inventions or groups of inventions which are not so linked as to form a single general inventive concept and therefore do not comply with the requirements of PCT Rule 13.1, the different inventions being the following:
 - 1.1 Invention 1 - Claims 1-9, 11-13, 15: An apparatus for storing and dispensing a material with a pressurised container comprising a valve with a dispensing valve stem having openings located circumferentially and being covered by a gasket until the stem is actuated.
 - 1.2 Invention 2 - Claims 1, 10: An apparatus for storing and dispensing a material with an adaptor comprising two female sockets connected by a passageway in the adaptor.
 - 1.3 Invention 3 - Claims 1, 14: An apparatus for storing and dispensing a material wherein a desiccant material is located in the pressurised gas of the container.
 - 1.4 Invention 4 - Claims 16-29: A method for storing and dispensing a material where the stem of a syringe is replaced with a needle and a on/off locking member is activated to the on position and material is dispensed.
- 2.1 The only feature common to claims 1-9, 11-13, 15; claim 10, claim 14 and claims 16-29 are the features of claims 1 and 16. These features are suggested for a

skilled person by the prior art as disclosed by document US 3 853 157 (D1). The skilled person knows, e.g. from US 6 053 373 (D2) or DE 8 704 600 U (D3) that the adaptor between the pressurised container and the syringe may be realised as a removable element connecting the stem of the valve with the stem of the syringe. Therefore it does not involve an inventive step for a skilled person to realise a removable adaptor. Alternatively, D3 (see figure 1) may form the closest prior art from which the subject-matter of claim 1 or 16 differs in that the second container is realised as a syringe. This modification is known from D1 or D2 (see figures 1) and thus the subject-matter of claims 1 or 16 do not involve an inventive step for a skilled person (Art. 33(3) PCT).

- 2.2 D1 also discloses or suggests the additional features of claims 2-9, 27 and 28 to a skilled person. Therefore these additional features cannot be special technical features.
- 3 The remaining features of claims 1-9, 11-13 and 15; 1, 10; 1, 14 and 16-29 solve four different problems by means of different potentially special technical features.
 - 3.1 The problem to be solved by the first invention is to provide a valve structure. The feature which solves this problem is the provision of openings in the stem of the valve which are covered by a gasket until the stem is actuated.
 - 3.2 The problem to be solved by the second invention is to provide a passageway between the syringe and the container. The feature which solves this problem is the provision of the adaptor with two female sockets connected by a passageway in the adaptor.
 - 3.3 The problem to be solved by the third invention is to ensure that the space between the container outer can and the inner bag remains dry. The feature which solves this problem is to provide desiccant material is located in the pressurised gas.
 - 3.4 The problem to be solved by the fourth invention is to provide a method for storing and dispensing a material while maintaining the purity of the material during dispensing. The feature which solves this problem is to activate the locking member to the on position after a needle has been placed on the syringe.

- 4 Since the problems to be solved by the four inventions and the features which solve these problems are different, the different technical features cannot be considered to be corresponding special technical features as required by PCT Rule 13.2.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:

D1 : US 3 853 157 A (MADAIO A,US) 10 December 1974 (1974-12-10)
D2 : US 6 053 373 A (SUTTON ET AL) 25 April 2000 (2000-04-25)
D3 : DE 87 04 600 U1 (COCON KUNSTSTOFFEN B.V., ARKEL, NL) 15 October 1987 (1987-10-15)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.
- 2.2 The document D3 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (cf. claim 1; page 7, last paragraph - page 8, paragraph 1; figure 1; the references in parentheses applying to this document) an:

Apparatus for storing and dispensing a material from a pressurized container while maintaining the integrity or purity of the material to be dispensed, the apparatus comprising:

- a) a pressurized container (24) holding the material to be dispensed, the pressurized container having a dispensing valve (28) with a dispensing valve stem having a distal end protruding from the pressurized container and a proximal end extending into the pressurized container;
- b) a second container (20) provided with 1) an on/off locking member (28) for permitting/or preventing flow of the material into or out of a chamber of the second container and 2) a stem having an end extending from the syringe for receiving material from the pressurized container; and

c) a removable adaptor (30, 32, 44) connecting the distal end of the dispensing valve stem protruding from the pressurized container (24) to the end of the stem extending from the second container (20) so as to establish a permissible flow path from one stem to the other stem;
so that upon activation of the on/off locking member (28) to the on position for permitting flow of material into the second container and activation of the dispensing valve to a dispensing mode material may flow from the pressurized container to the chamber of the second container.

The subject-matter of claim therefore differs from this known apparatus in that the second container is a syringe. Therefore, the subject-matter of claim 1 is new in the sens of Art. 33(2) PCT.

- 2.3 The problem to be solved by the present invention may therefore be regarded as to provide a second container with improved dosing capabilities.
- 2.4 The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons: Documents D1 (see figures 1-8) and D2 (see figures 1-4) disclose that a syringe is used as a second container. Since it is known from two prior art documents that the second container is a syringe, the skilled person knows that the second container according to D3 may be replaced by a syringe without an involvement of an inventive step. Therefore the subject-matter of claim 1 does not fulfill the requirements of Art. 33(3) PCT.

3 INDEPENDENT CLAIM 16

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 16 does not involve an inventive step in the sense of article 33(3)PCT.
- 3.2 Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 16, discloses (cf. claims 1, 6, 7, 12; column 4, lines 7-38; column 6, lines 13-31; column 6, line 64 - column 8, line 34; figures 1-8; the references in parentheses applying to this document) all features of claim 16 with the exception that the adaptor is removable and that the on/off locking member is shifted to in the stem of the syringe.

- 3.3 The subject-matter of independent claim 16 differs from the disclosure of D1 in that the adaptor is removable and that the on/off locking member is shifted to the stem of the syringe.
- 3.4 The problem to be solved by the present invention may therefore be regarded as to provide a separate adaptor and to disclose an improved place for the on/off locking member.

- 3.5 In view of D2 or D3 the solution proposed in claim 16 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

For a skilled person the feature that the adaptor is made removable is already known from the prior art, e.g. from D2 (cf. claims 1, 3-5; column 3, lines 6-28; figures 1 and 2) or D3 (cf. claim 1; page 7, last paragraph - page 8, paragraph 1; figure 1). Additionally, the removability of the adaptor is already at least suggested in D1 (see column 7, lines 27-30; figure 1), since there is a thread 31 provided between the adaptor and the container. Further, the provision of the on/off locking member in the syringe is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. In the present case, where it is essential that a contamination of the content of the syringe shall be avoided, it is clear for a skilled person that the valve formed by the apertures 39 and 41 (see figure 1 of D1) has to be shifted to the valve stem of the syringe to solve this problem. Since the removability of the adaptor and the positioning of the valve do not interact with each other and thus cannot have a synergetic effect, they may be looked at separately.

- 3.6 Therefore the features disclosed in D1 and the knowledge of the skilled person as disclosed in D2 or D3 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 16 thus cannot be considered inventive (Article 33(3) PCT).

4.1 DEPENDENT CLAIMS 2-9

Dependent claims 2-9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33 (3) PCT).

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4.2 DEPENDENT CLAIMS 11-13, 15, 17-29

The additional features of dependent claims 11-13, 15 and 17-29 are neither known nor rendered obvious by the prior art.

- 5** The vague and imprecise statement in the description on page 13 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.